



**SYSTEC & SERVICES**

KÖRBER SOLUTIONS

**Find the advantages of our portfolio for your company on the following pages.**

**Our portfolio allows us to always be on your side. We offer services and independent consulting to solve the challenges and requirements of our customers to their satisfaction. Our clients mainly operate in the regulated industries such as Pharma, BioTech, and Medical Devices.**

**WE  
ARE**

**ALWAYS**

**ON  
YOUR  
SIDE**

# DATA INTEGRITY

**Data is the main driver for the life science business. Complete and accurate data will eliminate any risks to the safety of patients or your business. We help you fulfill the cGMP Data Integrity requirements to mitigate these risks.**

## CLIENT BENEFITS

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- The use of the industry's best practices to assess and optimize your processes
- Shared knowledge of FDA, MHRA, and EMA regulatory requirements
- The application of ALCOA+ principles\*
- Audit readiness and data integrity thanks to the definition of action and risk mitigation plans
- A pragmatic approach for impactful and sustainable results

\* Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available

## CONTACT

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# MANUFACTURING EXECUTION SYSTEM

**In order to be up to date in manufacturing and to achieve quality, productivity and compliance goals, it is essential to use an MES. The selection, introduction, integration and operation of an MES will be more effective with the support of skilled, competent experts. We help clients to make the most out of their MES.**

## CLIENT BENEFITS

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- Strategic IT landscape consulting
- Requirement engineering
- Vendor selection
- Validation services
- Coaching and training, helpdesk, operations
- Change management
- SOP services
- Requirements engineering, using defined to-be processes and fit-gap analysis to figure out where to customize

## CONTACT

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# VALIDATION

**As experts with many years of experience in validation of computerized systems in the pharmaceutical industry, we offer a broad range of different compliance management services. Our CSV activities follow a clear process based on the V-model. We apply the GAMP-5 principles and cover all steps and documentation necessary for a compliant validation covering the regulatory requirements.**

## CLIENT BENEFITS

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- Domain experts in validation
- Coverage of the needs of small to mid-sized companies, up to the Global Top 10 pharma companies
- A GAMP-5 based, V-model applied solution
- A tool-based process
- CSV tailored to your requirements

## CONTACT

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# ENTERPRISE MANUFACTURING INTELLIGENCE

Lots of questions in the pharmaceutical industry can only be answered by combining data. EMI offers the possibility to display data from different production data sources (e.g. MES, Historian, LIMS, DCS, etc.) in standardized dashboards and reports. This optimizes runtimes, increases yields and meets regulatory requirements.

EMI is a solution that combines database knowledge, process expertise and tools.

## CLIENT BENEFITS

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- Focus on Use Cases
- Focus on Clear Business Benefit
- Compliance with regulatory requirements
- Validated Software
- Delivrance of a solution rather than a tool

## CONTACT

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# LION – LINE MANAGER

**LION is a flexible scalable solution for the common challenges of line connectivity. The customizable framework supports a variety of manufacturing line topologies.**

## CLIENT BENEFITS

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- A data-centric approach: one centralized system for all production units in a line
- Single HMI: one visualization for the operator in a production line
- Standard interfaces: data integrity by harmonizing interfaces between different systems
- Potential for process optimization: make more out of your data and optimize your line clearance, change over, OEE, etc. with new technologies (e.g. augmented reality)

## CONTACT

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# BUSINESS PROCESS MANAGEMENT

**A clear view of the processes is essential for a successful MES project. It helps keep the project on schedule, ensures high quality, and keeps costs down. We apply a standardized method to create clarity in the processes and offer tailor-made BPM services.**

## CLIENT BENEFITS

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- Clear view on as-is-processes (using our standardized “Process Landscape™”)
- Definition of to-be processes, considering
  - Customer requirements and expectations
  - Standardization based on ISA-88
  - Process harmonization
  - Strategic IT landscape analogous ISA-95
  - Strategic principles of automation integration
  - Available function sets of MES
  - Failure Mode Effects Analysis (FMEA)

## CONTACT

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